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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/334,537 06/16/99 ACHARI

R 719-163

EXAMINER

HM12/0109

GERALD T BODNER ESQ
HOFFMANN & BARON LLP
6900 JERICHO TURNPIKE
SYOSSET NY 11791

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/334,537

Applicant(s)

ACHARI ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Receipt of the Amendments and the Declaration by Charanjit R. Behl submitted

November 1, 2000 is acknowledged.

Claim Rejections 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hussain et al. (of record) for reasons stated in the prior office action.

3. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Merkus (US Patent 5,756,483 of record) for reason stated in the prior office action.

4. Claims 1-11, 14-15 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Merkus (US Patent 5,942,251 of record) for reasons stated in the prior office action.

Claim Rejections 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkus (US Patent 5,756,483 of record) for reason stated in the prior office action.

7. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkus (US Patent 5,756,483 of record) or Hussain et al. (of record).

8. Both Merkus et al and Hussain teach a pharmaceutical composition of morphine for nasal delivery with acidic pH as discussed in the prior office action.

9. The references do not teach expressly the particular pH herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to formulate a similar composition with the pH herein.

A person of ordinary skill in the art would have been motivated to formulate a similar composition with the pH herein because the pH herein (3.5, 4.0 or 5.0-6.0) is within the range or is close to the range disclosed in the prior art. (4.5 and 6.0). The optimization of the pH according to specific formulation is considered within the skill of artisan.

Response to the Arguments

10. Applicants' arguments and the declaration by Charanjit R. Behl have been fully considered, but are not persuasive as discussed below.

11. Regarding the statement by Dr. Behl and the remarks about the operability of Hussain (US Patent 4,464,378), note that every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability. See MPEP 716.07.

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12. Regarding the remarks about the teachings of Merkus, note that the fact is that the claimed composition (in low pH) is known in the art as shown by Merkus. Merkus does not teach that the low bioavailability is due to the low pH. In the contrary, Merkus use low pH for similar formulation. See example 2 and 3 in column 5 and 6 in '483.

Nothing unobvious is seen in the claimed invention.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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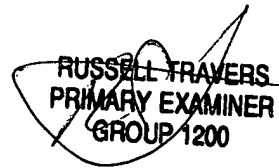
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

January 6, 2001



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200